## St. Michael's

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# Pocket P.E.P.

Clinical management of non-occupational and occupational exposure to blood borne pathogens



- A Pocket Reference -

January 2013 (next review: July 2013)

# STEP 1 TREAT EXPOSURE SITE & REPORT FOR ASSESSMENT

An individual who experiences an occupational or non-occupational exposure to blood borne pathogens needs to have immediate first aid treatment for any wound and a risk assessment for the likelihood of transmission of a pathogen.

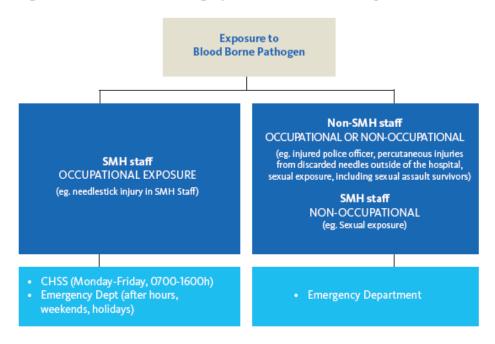
#### <u>SMH staff</u> with <u>occupational</u> exposures should immediately:

- Remove any contaminated clothing
- Allow wound to bleed freely
- · Wash the area thoroughly with soap and water
- · If exposed area involves the eyes, nose or mouth, thoroughly flush well with water
- Report the incident to his/her immediate supervisor and complete the Blood Borne Pathogen Exposure Report. If the source patient is known, it is important to record the source patient's full name and hospital number in the exposure report.
- Proceed immediately for risk assessment:
  - During Business Hours (Monday to Friday, 0700-1600h):
    - Corporate Health and Safety Services (2 Shuter, Ext 5013)
  - · After hours, weekends, holidays:
    - · Emergency Department

#### non-SMH staff with occupational exposures and all non-occupational exposures:

· should proceed immediately to the ED for treatment and assessment.

#### Algorithm for Presentation Following Exposure to a Blood Borne Pathogen



## STEP 2

#### ASSESS THE EXPOSURE RISK

Many factors contribute to a significant exposure and a higher risk of transmission of a blood borne pathogen, including the type of body fluid involved, the type of injury that occurred, the size of the inoculum, and the attributes of the source patient. All of the following information should be obtained and recorded.

#### a. Body fluid: Body fluids considered potentially infectious include:

- plasma cerebrospinal fluid
- semen synovial fluid
- pleural fluid
   amniotic fluid
- peritoneal fluid
- pericardial fluid

Body fluids <u>NOT</u> considered potentially infectious <u>unless</u> visibly bloody include: (However: HBsAg is found in feces, nasopharyngeal washings, saliva and sweat)

- Feces
- sputum
- urine

- nasal secretions
- sweat
- vomitus
- saliva tears

#### b. Type of Injury/Exposure

- · percutaneous skin puncture or laceration by needle or sharp object
- mucosal splash to mucous membranes (eg. eyes, nose, mouth)
- · cutaneous contact through nonintact skin (eg. cuts, dermatitis)

#### c. Inoculum size

- volume of infectious fluid involved (eg. hollow bore vs. solid needle; large volume vs small volume splash)
- · viral titre in the infectious fluid if known (eg. well controlled disease vs. poorly controlled)

#### d. Source patient

- unknown HBV, HCV or HIV status
- positive for HBV, HCV, and/or HIV
- negative with risk factors (eg. men who have sex with men, multiple sexual partners, injection drug user, tattoo/body piercing, recipient of blood transfusion before 1986 for HIV or 1990 for HCV in Canada)
- negative with no risk factors

#### **Estimated risk of transmission:**

#### Following percutaneous exposure to blood or potentially infectious fluid:

- hepatitis B: 6-30%
- hepatitis C: 3-10%
- HIV: 0.3% (0.09% for mucous membrane exposure)

#### Estimated Per-Act Risk for Acquisition of HIV

Exposure route	Risk per 10,000 exposures to an infected source	
Blood transfusion	9,000 (90%)	
Needle-sharing injection-drug use	67 (0.67%)	
Receptive anal intercourse	50 (0.5%)	
Percutaneous needle stick	30 (0.3%)	
Receptive penile-vaginal intercourse	10 (0.1%)	
Insertive anal intercourse	6.5 (0.065%)	
Insertive penile-vaginal intercourse	5 (0.05%)	
Receptive oral intercourse	1 (0.01%)	
Insertive oral intercourse	0.5 (0.005%)	

# STEP 3 ASSESS THE SOURCE & PERFORM BASELINE TESTING

Since serologic testing of the source patient for HBV, HCV and HIV is the most reliable method to assess the risk of exposure, this is strongly recommended. Ascertain if the <a href="mailto:exposed">exposed</a> individual is willing to be tested for antibody to HBV, HCV and HIV. If the <a href="mailto:exposed">exposed</a> individual is not willing to be tested, do not test the source patient.

#### **Laboratory Testing of source patient:**

#### If the source patient is KNOWN:

Test patient for HBsAg, HCV Ab, and HIV Ab

- · Informed consent must be obtained
- · If source is a neonate, testing should be done on mother
- If the source patient does not consent to testing and is at epidemiological risk for infection
  with HBV, HCV and/or HCV, follow the protocol for a positive source. However, an application
  can be made to the medical officer of health (MOH) requiring mandatory blood testing by the
  source patient if the exposure occurred while the SMH staff member was providing emergency
  health care services or emergency first aid to the source. The application process can be found
  at: http://www.health.gov.on.ca/english/providers/legislation/bill 105/105 mn.html

#### If the source patient is UNKNOWN or source cannot be tested:

Consider the likelihood of a bloodborne pathogen infection among patients in the exposure setting, eg, what is the community infection rate? Does the source have risk factors for infection?

#### **BASELINE TESTING in exposed patient:**

- Blood will be drawn for antibody to HBV, HCV and HIV
  - If baseline testing in exposed patient is POSITIVE:
  - Give appropriate counseling, encourage medical referral, and follow appropriate hospital policies if patient is SMH staff
  - If baseline testing in exposed patient is NEGATIVE and:

#### The source test result is negative:

- no further action is usually necessary; however, the individual should be counseled about the possibility that a high-risk source may be in the "window period" of acute infection. If that is a strong possibility, further follow-up serology may be recommended in consultation with the physician.
- the individual should initiate the 3-dose vaccine for hepatitis B if not already immune

#### The source test result is positive:

follow the procedure for HBV, HCV and/or HIV exposure

#### The source test result is unknown:

- follow the procedure for HBV, HCV and/or HIV exposure
- Consider testing for pregnancy and sexually transmitted infections (eg. gonorrhea, chlamydia, syphilis) as clinically indicated



### PEP MANAGEMENT - HBV EXPOSURE

Management of potential hepatitis B exposure is dependent on the vaccination and antibody status of the exposed individual.

#### If the antibody status of the individual is unknown:

 immediately draw blood for anti-HBs (and label as "needlestick") prior to giving hepatitis B immune globulin or vaccine. For an individual who is immune, no further action is required. An immune individual:

• has documented anti-HBs at any time after completing the hepatitis B vaccination

- · has had natural exposure to hepatitis B and has HB core or HB surface antibodies

For an individual who is <u>not immune</u>, hepatitis B treatment and prophylaxis is required.

A non-immune individual:

- · has never been vaccinated
- · is a known non-responder to the hepatitis B vaccination series (ie. tested negative to anti HBs after two complete series of the hepatitis B vaccine)

Vaccination Status	HBV Status of Source				
of Exposed	HBsAg Negative	HBsAg Positive	Unknown		
Unvaccinated					
Anti-HB Ab ≥10mIU/mL	No further action required	No further action required	No treatment required		
Anti-HB Ab <10mIU/mL	Initiate vaccine series	HBIG x 1 Initiate vaccine series	If high risk exposure setting, treat as if source was HBsAg positive; otherwise, treat as if source was HBsAg negative		
Vaccinated					
Anti-HB Ab ≥10mIU/mL (ever)	No further action required	No further action required	No treatment		
Anti-HB Ab <10mIU/mL	Completed 2 vaccine series • No treatment Completed 1 vaccine series • initiate second vaccine series	Completed 2 vaccine series • HBIG x 1, repeat in 1 month Completed 1 vaccine series • HBIG x 1 • initiate second vaccine series	If high risk exposure setting, treat as if source was HBsAg positive; otherwise, treat as if source was HBsAg negative		
Anti-HB Ab level unknown	Measure Anti-HB Ab level and if:  Anti-HB Ab ≥ 10mIU/mL  • No treatment  Anti-HB Ab < 10mIU/mL  Completed 2 vaccine series  • No treatment  Completed 1 vaccine series  • initiate second vaccine series	Measure Anti-HB Ab level and if:  Anti-HB Ab ≥ 10mIU/mL  No treatment  Anti-HB Ab < 10mIU/mL  Completed 2 vaccine series  HBIG x 1, repeat in 1 month  Completed 1 vaccine series  HBIG x 1  initiate second vaccine series	If high risk exposure setting, treat as if source was HBsAg positive; otherwise, treat as if source was HBsAg negative		
Currently completing	g first vaccination series				
Received at least 2 doses	Complete vaccine series	Measure Anti-HB Ab level and administer 1 dose of vaccine  If Ab < 10mIU/mL  HBIG x 1  give final dose at time it would be due if infection has not occurred  If Ab ≥ 10mIU/mL  complete vaccination series	If high risk exposure setting, treat as if source was HBsAg positive; otherwise, treat as if source was HBsAg negative		
Only received 1 dose	Complete vaccine series	Measure Anti-HB Ab level and administer HBIG x 1 and 1 dose of vaccine  If Ab < 10mIU/mL  • retest in 4 weeks and complete vaccine series if infection has not occurred  If Ab ≥ 10mIU/mL  • complete vaccination series	If high risk exposure setting, treat as if source was HBsAg positive; otherwise, treat as if source was HBsAg negative		

#### The treatment of an individual who is not immune may include one or both of the following:

#### a. Hepatitis B immune Globulin (HBIG)

When indicated, HBIG should be given as soon as possible, preferably within 24 hours after the exposure. Efficacy decreases substantially when it is given >48 hours post-exposure, and it is unlikely to be effective after 7 days. Dosage is given as 0.06 mL/kg body weight, to a maximum of 5 mL, administered intramuscularly equally at two administration sites. Dose should be repeated in one month in a known non-responder.

#### b. Hepatitis B vaccine series

A 3-dose series is indicated in the individual who has not been immunized. Doses should be administered at a site separate from HBIG if co-administered. A second 3-dose series of the hepatitis B vaccination is indicated in an individual who is non-immune after the first course. Completion of the vaccination is indicated in the individual who started the vaccination series, but did not complete all three doses.

#### In addition to receiving general counseling, the non-immune individual should be:

- · assessed for HBV seroconversion at least 2 months after exposure
- be counseled on the signs and symptoms of hepatitis that may occur within 6 weeks to 6
  months after exposure (eg. fatigue, loss of appetite, abdominal discomfort, jaundice,
  change in colour of urine and stool, rash, sore joints)



### PEP MANAGEMENT - HCV EXPOSURE

There is no prophylactic treatment currently available for a person exposed to hepatitis C. Data do not support the use of immune globulin (IG) or antiviral agents, and thus these agents cannot be recommended.

#### The individual should be:

- tested for HCV antibody as soon as possible after exposure and, if negative, again at 3 and 6 months.
- test for HCV RNA at 4-6 weeks if earlier diagnosis of HCV infection is desired
- counseled on the risk of becoming infected (eg. transmission risk is estimated at 3-10%)
- counseled on the signs and symptoms of hepatitis that may occur within 6 weeks to 6
  months after exposure (eg. fatigue, loss of appetite, abdominal discomfort, jaundice,
  change in colour of urine and stool, rash, sore joints)

## STEP 4c

### PEP MANAGEMENT - HIV EXPOSURE

Management of a potential HIV exposure is dependent on the nature and risk of the exposure. PEP is not needed for exposure to stool, urine, tears, saliva, nasal secretions, vomitus, <u>unless</u> bloody. PEP may be needed (depending on type of exposure) if the source material is:

- blood, bloody fluid, semen or vaginal secretions,
- cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids
- tissue
- an instrument contaminated with one of the above substances

#### Management of HIV Exposure Based on Occupational Exposure and Source

	SOURCE INDIVIDUAL				
		HIV Positive			
TYPE OF EXPOSURE	HIV Negative	Lower titre exposure eg., say mptomatic HIV infection and low viral load count* (i.e.1500 copies.mL) ± history of HIV medication exposure	Higher titre exposure eg., advanced AIDS, primary HIV infection/ acute seroconversion, high or increasing viral load or law CD4 count* and source has not or is not currently taking HIV medication	and source has taken or  on/ is currently taking HIV medication nta htsory of source patient should be obtained. If there	
Intact Skin only	No PEP	No PEP	No PEP	No PEP	No PEP
Mucous membrane or n	onintact ski	n exposure eg, chappe	d skin, dermatitis, abras	sion, open wound	
with a <u>small</u> volume eg, few drops for short duration ie. less than several minutes	No PEP	No PEP or Consider Basic regimen	Basic regimen	Basic regimen and Consult ID	No PEP
with a large volume or major blood splash eg, several drops, major blood splash and/or longer duration ie. several minutes or more.	No PEP	Basic regimen	Expanded regimen	Expanded regimen and Consult ID	Consider Basic regimen (in settings where exposure to HIV-infected persons is likely)
Percutaneous/sharps e	ercutaneous/sharps exposure				
with solid needle or superficial injury eg, solid needle, superficial scratch	No PEP	Basic regimen	Expanded regimen	Expanded regimen and Consult ID	Consider Basic regimen (in settings where exposure to HIV-infected persons is likely)
With large-bore hollow needle or more severe injury eg deep puncture, visible blood on device, or needle used in source patient's artery orvein. (The combination of these severity factors eg large-bore hollow needle and deep puncture) contribute to an elevated risk for transmission if the source patient is HIV-positive.)	No PEP	Expanded regimen	Expanded regimen	Expanded regimen and Consult ID	Consider Basic regimen (in settings where exposure to HIV-infected persons is likely)

\*Examples are used as surrogates to estimate the HIV titre in an exposure source for purposes of considering PEP regimens and do not reflect all clinical situations that may be observed. Although a high HIV titre in an exposure source has been associated with an increased risk for transmission, the possibility of transmission from a source with low HIV titre also must be considered.

#### Management of HIV Exposure Based on Non-Occupational Exposure and Source

	SOURCE		
	HIV POSITIVE	HIV Status Unknown	
Negligible Exposure			
<b>Exposure</b> of vagina, rectum, eye, mouth, or other mucous membrane, intact or nonintact skin, or percutaneous contact <b>With</b> urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood <b>Regardless</b> of the known or suspected HIV status of the source	No PEP	No PEP	
Substantial Exposure, >72 hours since exposure			
Exposure of vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact With blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood When the source is known to be HIV-infected	Case-by-case determination	No PEP	
Substantial Exposure, ≤72 hours since exposure			
<b>Exposure</b> of vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact <b>With</b> blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood <b>When</b> the source is known to be HIV-infected	PEP Expanded Regimen	Case-by-case determination	

#### HIV Post Exposure Prophylaxis Drug Regimens

Retrospective case-control data suggests that post-exposure use of zidovudine reduces the risk of HIV transmission by 79%. Use of combination antiretrovirals may further reduce the risk of infection. If the source is found to be negative, PEP should be discontinued.

#### The Basic regimen consists of:

- Truvada (tenofovir 300mg/emtricitabine 200mg) 1 tablet once daily
  - Dose based on adequate renal function (CrCl ≥ 50ml/min)
  - · Truvada side effects include nausea, headache, diarrhea, fatigue, acute renal failure (rare)

#### The Expanded regimen consists of:

- Truvada (tenofovir 300mg/emtricitabine 200mg) 1 tablet once daily
  - Dose based on adequate renal function (CrCl ≥ 50ml/min)
  - Truvada side effects include nausea, headache, diarrhea, fatigue PLUS
- Kaletra tablets (lopinavir/ritonavir 200/50mg) 4 tablets once daily
  - Kaletra side effects include diarrhea, nausea, asthenia, abdominal pain, ↑ lipids, ↑ LFTs

#### Other "expanded regimens" that could be considered include:

- Truvada 1 tablet once daily + Atazanavir 300 mg once daily + Ritonavir 100 mg daily
- Truvada 1 tablet once daily + Darunavir 800 mg once daily + Ritonavir 100mg daily
- Truvada 1 tablet once daily + raltegravir 400 mg twice daily

If available, the source-person should be interviewed for his/her history of antiretroviral medication use to help avoid prescribing medications to which the virus is likely to be resistant. If the source patient is HIV positive and has been on antiretroviral therapy, start the recommended expanded regimen <u>and</u> consult the Infectious Disease/HIV service. Initiation of PEP should not be delayed pending this consultation. Modifications can be made later.

An initial supply of medications (5 days) will be provided by CHSS or ED. **If deemed necessary, therapy should be continued for 28 days** and a prescription will be provided to the individual in follow-up.

#### Descriptions, Cautions and Contraindications for Using Truvada or Kaletra

Careful consideration should be made to drug interactions when using antiretrovirals with other medications, especially those that may compromise the activity of HIV medications and those that may be affected by the antiretrovirals.

#### Truvada

Emtricitabine and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion. Since emtricitabine and tenofovir are primarily eliminated by the kidneys, coadministration of Truvada with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of emtricitabine, tenofovir, and/or other renally eliminated drugs.

Contraindicated	Use with Caution	
Patients with severe renal insufficiency	Patients with renal insufficiency (dose adjustment required)	
(creatinine clearance of <30mL/min, including patients requiring hemodialysis)	didanosine Antiretrovirals atazanavir (without ritonavir)	

#### **Kaletra**

Kaletra is a substrate and potent inhibitor of the P450 isoform CYP3A enzyme. Caution should be used when co-administering Kaletra and CYP3A4 enzyme inducers, inhibitors, or substrates with narrow therapeutic indices. If uncertain, please contact an ID/HIV specialist or pharmacist. The chart below lists some of the major drug interactions identified; other drug interactions may exist.

Contraindicated		Use with Caution		
		Patients with severe hepatic impairment		
α-1 antagonist	alfuzosin	A ptiarrhythmics bepridil	amiodarone propafenone	
Antibiotic	fusidic acid			
Antihistamines	astemizole terfenadine	-	lidocaine (systemic)	
Antimycobacterial	rifampin	Antibiotics	clarithromy cin rifabutin	
Ergot derivatives	dihydroergotamine ergonovine ergotamine methylergonovine	Anticoagulants	warfarin	
GI motility agents	cisapride	Anticonvulsants	carbamazepine phenobarbital phenytoin	
Herbal products	St. John's Wort (Hypericum perforatum)	Antifungals	Itraconzole >200mg/d ketoconazole voriconazole	
HMG-CoA Reductase Inhibitors	lovastatin simvastatin	Calcium channel blockers	amlodipine felodipine nifedipine	
Long acting beta-agonist	salmeterol	Cardiotonic glycoside	digoxin	
Neuroleptic	pimozide	Corticosteroids (systemic and inhaled)	dexamethasone fluticasone	
Sedative/hypnotics	midazolam triazolam	Immunosuppressants	cyclosporine tacrolimus rapamycin	
PDE5 inhibitors	sildenafil (contraindicated when used for pulmonary hypertension) vardenafil	PDE5 inhibitors	sildenafil tadalafil	
		Oral/Patch contraceptive	norethindrone ethinyl estradiol	
		Narcotic analgesic	fentanyl methadone	
		HMG-CoA Reductase Inhibitors	atorvastatin or rosuvastatin>10mg/d	
		Psychotropics	citalopram sertraline quetiapine trazadone	



#### General

- If the source is known, suspected or found to be positive for HBsAg, HCV Ab, and/or HIV Ab, the individual should not:
  - donate blood, semen, tissues, or organs
    - es, or organs
  - · have unprotected sexual intercourse
- share razors or toothbrushes
   breastfeed (only if source may be HIV positive)
- All patients started on PEP should be referred to the Positive Care Clinic (416-864-5696)
- If started on PEP, the patient should receive <u>additional baseline bloodwork</u> including CBC, creatinine, ALT

#### HBV exposure follow-up testing and counseling

- 8 weeks HBV serology if vaccinated post-exposure
- counsel regarding signs and symptoms of hepatitis that may occur within 6 weeks to 6 months after exposure (eg. fatigue, loss of appetite, abdominal discomfort, jaundice, change in colour of urine and stool, rash, sore joints)

#### HCV exposure follow-up testing and counseling

- · 3 and 6 months HCV serology, ALT
- · test for HCV RNA at 4-6 weeks if earlier diagnosis of HCV infection is desired
- counsel regarding signs and symptoms of hepatitis that may occur within 6 weeks to 6 months after exposure (eg. fatigue, loss of appetite, abdominal discomfort, jaundice, change in colour of urine and stool, rash, sore joints)

#### HIV exposure follow-up testing and counseling

- 6 weeks, 3 months, 6 months (and 12 months only if HCV conversion occurs) HIV serology
- Counsel regarding signs and symptoms of HIV infection that may occur within 2-14 weeks after exposure (eg. "flu-like" symptoms, weight loss, skin rash, fever, lymphadenopathy, fatigue)
- If PEP was provided, monitor for drug toxicity at 2 weeks (CBC, creatinine, ALT)

#### STI follow-up testing

- · gonorrhea, chlamydia (urine, rectal, throat) depending on exposure
- · syphilis serology at 6 weeks
- consider eligibility for hepatitis A vaccination as a sexual health promotion intervention

#### References

Centers for Disease Control and Prevention. (2005, January 21). Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States. *Morbidity and Mortality Weekly Report*, 54(RR-2).

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